UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

November 12, 2013

MEMORANDUM

SUBJECT: Efficacy Review for Vesta;
EPA Reg. No. 3573-OO;
DP Barcode: D413026

FROM: Karen M. Hill, Ph.D.
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11/12/13

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TO: Velma Noble RM31/ Emilia Oiguenblik
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: The Procter and Gamble Co.
5299 Spring Grove Avenue
Cincinnati, OH. 45217

FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Didecyl Dimethyl Ammonium Chloride	0.33%
Inert Ingredients	99.67%
Total	100.00%

I. BACKGROUND:

The applicant is seeking to register the product Vesta (EPA Reg. No. 3573-OO) as a disinfectant with bactericidal, virucidal, and fungistatic (not fungicidal) activity for use on hard non-porous surface, a non-food contact sanitizer for use on hard non-porous surfaces, and a soft surface sanitizer. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

The data package contained a transmittal letter from the registrant to the Agency dated June 14, 2013, a Confidential Statement of Formula (EPA Form 8570-4), a Data Matrix (EPA Form 8570-35), a proposed product label, fourteen efficacy studies (MRIDs 490817-14 through 490817-27) with a Statement of No Data Confidentiality Claims embedded in each MRID.

II. USE DIRECTIONS:

The ready to use spray product Vesta is intended to be used as a disinfectant on hard non-porous surfaces and as a soft surface sanitizer. The product is proposed to be used to sanitize soft surfaces such as household fabrics, upholstery, drapes, curtains, mattresses, bedding, shower curtains, bath mats, rugs and everyday fabrics including clothes, shoes, socks, and gym bags. The product is proposed to be used to disinfect hard, non-porous surfaces in households and other environments such as cabinets, toilets, bathtubs, floors, garbage cans, walls, work surfaces, glass, glazed ceramic, porcelain tile, linoleum, plastic, vinyl, non-wood furniture, and cabinets.

Directions on the proposed label provide the following information regarding preparation and use of the product:

(Fabric Applications)
To refresh (deodorize) fabrics, spray on fabrics until slightly damp to eliminate odors. For a noticeably fresh home, spray fabrics, carpets, and air all around your home.

To sanitize soft surfaces (fabrics), clean heavily soiled areas before application. From a distance of 6-8 inches, spray a spot (2" x 2" area) evenly until damp to kill bacteria. Fabric must remain wet for 5 minutes. [Effective against *Enterobacter aerogenes, Proteus mirabilis, Escherichia coli*, and *Staphylococcus aureus*.]

To kill (control)(eliminate) odor-causing bacteria on soft surfaces(fabrics): Clean heavily soiled areas before application. From a distance of 6-8 inches, spray evenly until damp to kill bacteria. Fabric must remain wet for 5 minutes. (As item dries, odors are eliminated, and bacteria are killed.) [Effective against *Enterobacter aerogenes, Proteus mirabilis, Escherichia coli,* and *Staphylococcus aureus*.]

For mold/mildew prevention (control)(inhibition): For heavily soiled areas, a pre-cleaning step is required. From a distance of 6-8 inches, spray surface until thoroughly wet. Fabric must remain wet for 5 minutes. Repeat treatment every 14

days, or more often if new growth appears. [Effective against *Aspergillus niger* and *Penicillium variabile*].

(Hard Non-Porous Surfaces)
For Cleaning (deodorizing): Spray 6-8 inches from surface. Wipe dry with a dry paper towel or lint free cloth.

For [Bactericidal & Virucidal] Disinfection: For heavily soiled areas only, a pre-cleaning step is required. For hard non-porous surfaces, spray surface from 6-8 inches until thoroughly wet. Let stand for 5 minutes before wiping [to kill bacteria and viruses]. [Effective against *Enterobacter aerogenes, Proteus mirabilis, Escherichia coli, Staphylococcus aureus*, and Influenza A].

For mold/mildew prevention (control)(inhibition): For heavily soiled areas, a pre-cleaning step is required. For hard non-porous surfaces, spray surface from 6-8 inches until thoroughly wet. Let stand for 5 minutes before wiping. Repeat treatment every 14 days, or more often if new growth appears. [Effective against *Aspergillus niger*.]

III. AGENCY STANDARDS:

Disinfectants for Use on Hard Surfaces Against a Broad Spectrum of Bacteria:
The effectiveness of disinfectants for use on hard surfaces must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products), AOAC Hard Surface Carrier Test (for water soluble powders and liquid products), or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers for each of three samples, representing three different batches, one of which should be ≥60 days old, should be tested against both *S. enterica* (ATCC 10708) and *S. aureus* (ATCC 6538).

For Germicidal spray products (aerosol or pump) and volatile liquid products test procedure, the Agency recommends the AOAC International Germicidal Spray Products as Disinfectants test. Sixty carriers for each of three samples, representing three different batches, one of which should be ≥60 days old, should be tested against both *S. enterica* (ATCC 10708) and *S. aureus* (ATCC 6538).

For the AOAC International Use-Dilution Methods, the Germicidal Spray Products as Disinfectants test, and single-use towelettes, the product should kill the test microorganisms on 59 out of each set of 60 carriers/slides in ≤ten minutes. In addition, per the 2009 AOAC revisions for the Use-Dilution Method, the mean log density for *S. aureus* is to be at least 6.0 (corresponding to a geometric mean density of 1.0×10^6); a mean log density <6.0 invalidates the test. For the AOAC International Hard Surface Carrier Test Methods, the product should kill the test microorganisms on 58 out of each set of 60 carriers in ≤ten minutes. For the Hard Surface Carrier Test, the dried carrier counts should be $0.5 - 2.0 \times 10^6$ for *Salmonella enterica* and $1 - 5 \times 10^6$ for *Staphylococcus aureus*.

Disinfectants for Use on Hard Surfaces Against Broad Spectrum of Bacteria (Additional Bacteria):

Water-soluble powders and non-volatile liquid products test procedure. The Agency recommends the use of the AOAC International Use-Dilution Methods or the AOAC International Hard Surface Carrier Test Methods. Ten carriers should be tested against each specific bacterium for each of two samples representing two different batches. The product should kill all the test microorganisms on all carriers in ≤ten minutes. The minimum carrier count to make the test valid should be 1×10^4.

Virucides:
The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. If the product is intended to be represented as a one-step virucidal, an appropriate organic soil (i.e.- 5 percent blood serum) should be included with the viral inoculum.

Sanitizers (For Non-Food Contact Surfaces):
The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Products for control of mold and mildew on surfaces (Mildewstats / Fungistats):
The efficacy of products intended to prevent the growth of mold and mildew is greatly affected by the type of surface to which the products are applied. Test methods for representative surfaces are "Fabric Mildew Fungistatic Test Method", "Hard Surface Mildew Fungistatic Test Method", "Leather Mildew Fungistatic Test Method", and "Wood Block Mildew Fungistatic Test Method". These methods are found in Subdivision G section 93-30. If the surfaces to be treated, or the methods of application, or the organisms to be controlled by the product, are not the same as those indicated in the method, the method should be modified to reflect these differences. Modifications should also be made so that the method will more clearly reflect actual in-use conditions (including any specialized use situations).

Mildewstats should also be tested to determine whether or not bleaching, staining, spotting or other undesirable effects occur on the surfaces, articles, and materials to be protected.

Hard Surface Mildew Fungistatic Test:
This method is intended to be used in supporting fungistatic claims for the control, treatment, or prevention of fungi and subsequent mildew growth on hard surfaces. Use of this test method in no way supports claims for use of a product as a fungicide. The test is to be conducted on 10 glazed ceramic tiles for each of two product lots against *Aspergillus niger* (ATCC 6275). Ten untreated glazed tiles are to be used as the control, on which greater than 50% of each tile is to be covered with fungal growth after 7 days for the test to be considered valid. Growth observations are to be made visually after 7 days of incubation. If no visible growth is evident at the end of the test period, examination at a 15X magnification must take place. A product dosage is considered acceptable when all ten treated replicates are free of fungal growth.

Fabric Mildew Fungistatic Test Method: The test is to be conducted on cotton muslin strips cut 25 by 75 mm from 136 to 203 g/m^2 (4 to 6 oz./yd.^{2}) fabric. The strips should be autoclaved sterilized. The product is to be tested against *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333). Soak fabric strips in Nutrient broth for three minutes or until saturated. Remove excess liquid and allow fabric strips to dry before proceeding with application of the test product. Both sides of ten strips for each batch should be spray treated. The application specifications including spray distance from nozzle, degree of wetness, draining conditions, and drying procedures should be reported. Equal volumes of well-agitated conidial suspensions of *Aspergillus niger* and *Penicillium variable* using a DeVilbiss atomizer (or equivalent) should be sprayed on both sides of each fabric strip. The fabric samples are suspended in individual 500 mL jars containing 90 mL water and incubated at approximately 28°C with the caps tightened and backed off 1/8 turn to allow for ventilation. Observations are made weekly for four weeks or until treatments fail and abundant growth occurs on all treated strips (at 7, 14, or 21 days). Where no growth is visually evident at the end of the test period, examination at approximately 15X magnification must be conducted to confirm the absence or establish the presence of subvisual growth. The untreated control strips (10 strips) must have a minimum of 50% of their surface area covered with fungal growth after 7 days to consider the test valid. The acceptance criterion requires that all ten treated replicates per batch must be free of fungal growth. The directions for use must specify retreatment every 7, 14, or 21 days, as necessary depending on the length of time that all of the test strips remain free of mildew growth. Labeling of products which do not permit growth after four weeks incubation must specify a retreatment schedule, such as "repeat as necessary when new growth appears", and should indicate that treatments should be effective for at least 28 days.

Spot Soft Surface Sanitization:
The study is designed to evaluate the antimicrobial efficacy of spray application sanitizers on pre-cleaned or lightly soiled, non-food contact soft surfaces. For sanitizer products intended for use on soft, non-food contact surfaces, a fabric carrier method is used to generate efficacy data. The test system proposed is a modification of the ASTM approved method for the evaluation of the antimicrobial efficacy of sanitizers on non-food contact surfaces. The method is modified for spray product application. The Agency recommends the use of The American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact

Surfaces (ASTM E1153-03). Three product samples, representing three different batches, one of which should be at least 60 days old, should be tested against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048). The ASTM method states "an average of at least 7.5×10^5 organisms must have survived the inoculated control squares for the test to be valid." Two different fabric types should be tested. The fabrics should represent natural fabrics, such as cotton, and synthetic fabrics, such as polyester or rayon. A film of bacterial cells, dried on fabric carriers, is exposed to the test substance for a specified contact time. After exposure, the carriers are transferred to vessel containing neutralizing subculture media and assayed for survivors. Appropriate viability and sterility of organism population and neutralization controls are performed. Carrier type claimed on the label must be consistent with the test system. The test material meets effectiveness requirements of kill an average of at least 99.9% (3 log reduction) of the required organism on the 5 replicate carriers within 5 minutes. Controls must always meet the stipulated criteria.

Supplemental Claims:
An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV. Brief Description of the Data:

1. MRID 490817-14 "AOAC Germicidal Spray Method," Test Organism: *Salmonella enterica* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538) for product Vesta, by Joshua Luedtke, M.S. Study conducted at ATS Labs. Study completion date – July 6, 2012. Project Number A13414.

The study was conducted against *Salmonella enterica* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538). Two lots of test substance, Lot # SS1684 and Lot # SS1685, were tested using the provided ATS Laboratory Protocol No. PG30050312.GS.1 marked as proprietary information. The product was received as ready to use (RTU) trigger spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula submitted with this application. The active ingredient concentration reported on the certificate of analysis (COA) for Lot # SS1684 was 0.2977% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250) and for Lot # SS1685 was 0.2956% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250). A culture of the challenge microorganism was prepared from the initial broth suspension by more than three but less than thirty daily consecutive transfers of one loopful (10 µL) of culture in 10 mL of the appropriate growth medium Nutrient broth. For the last culture transfer, a sufficient number of tubes containing 20 mL of culture were inoculated with 10µL of culture and incubated 48 - 54 hours. The cultures were allowed to stand for ≥ 10 minutes prior to removing the upper portion of the culture leaving behind clumps and debris and transferring it to a sterile vessel for use in testing. Fetal bovine serum was added to the culture to achieve a final 5% organic soil load. Individual glass slide carriers (18 mm x 36 mm) were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the entire surface of the slide. For *Staphylococcus aureus*, the slides were allowed to dry for 38 minutes at 35-37°C at 50% relative humidity. For *Salmonella enterica*, the slides were allowed to dry for 30 minutes at 35-37°C at 50% relative humidity. For each lot of test

substance, the test carriers were sprayed (using 2 sprays) in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 5 minutes at 20°C at 55% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred to 20 mL of neutralizing solution containing Letheen Broth + 0.14% Lecithin + 1.0% Tween 80. All subcultures were incubated for 48±2 hours at 35-37° prior to the examination for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: No protocol deviations or amendments were required for this study.

2. **MRID 490817-15 "AOAC Germicidal Spray Method," Test Organism: *Salmonella enterica* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538) for product Vesta, by Anne Stemper, B.S. Study conducted at ATS Labs. Study completion date – Aug 22, 2012. Project Number A13831.**

The study was conducted against *Salmonella enterica* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538). One lot of test substance, Lot # SS1691, was tested using the provided ATS Laboratory Protocol No. PG30071212.GS.2 marked as proprietary information. The product was received as ready to use (RTU) trigger spray. The test lot was prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula submitted with this application. The active ingredient concentration reported on the certificate of analysis (COA) for Lot # SS1691 [dated July 2012] was 0.2985% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250). A culture of the challenge microorganism was prepared from the initial broth suspension by more than three but less than thirty daily consecutive transfers of one loopful (10 µL) of culture in 10 mL of the appropriate growth medium Nutrient broth. For the last culture transfer, a suspension of sufficient number of tubes containing 20 mL of culture were inoculated with 10µL of culture and incubated 48 - 54 hours. The cultures were allowed to stand for ≥ 10 minutes prior to removing the upper portion of the culture leaving behind clumps and debris and transferring it to a sterile vessel for use in testing. Fetal bovine serum was added to the culture to achieve a final 5% organic soil load. Individual glass slide carriers (18 mm x 36 mm) were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the entire surface of the slide. For *Staphylococcus aureus*, the slides were allowed to dry for 39 minutes at 35-37°C at 55.7% relative humidity. For *Salmonella enterica*, the slides were allowed to dry for 30 minutes at 35-37°C at 55.7% relative humidity. The test carriers were sprayed (using 2 sprays) in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 5 minutes at 20°C at 58% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred to neutralizing solution containing 20 mL of Letheen Broth + 0.07% Lecithin + 0.5% Tween 80. All subcultures were incubated for 48±2 hours at 35-37° and stored at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: No protocol deviations or amendments were required for this study.

3. **MRID 490817-16 "AOAC Germicidal Spray Method," Test Organism: *Proteus mirabilis* (ATCC 7002) for product Vesta, by Nicole Albert, B.S.**

Study conducted at ATS Labs. Study completion date – Sept 26, 2012. Project Number A13383.

The study was conducted against *Proteus mirabilis* (ATCC 7002). Two lots of test substance, Lot # SS1684 and Lot # SS1685, were tested using the provided ATS Laboratory Protocol No. PG30050312.GS.2 marked as proprietary information. The product was received as ready to use (RTU) trigger spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula submitted with this application. The active ingredient concentration reported on the certificate of analysis (COA) for Lot # SS1684 was 0.2977% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250) and for Lot # SS1685 was 0.2956% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250). A culture of the challenge microorganism was prepared from the initial broth suspension by more than three but less than thirty daily consecutive transfers of one loopful (10 µL) of culture in 10 mL of the appropriate growth medium Nutrient broth. For the last culture transfer, a suspension of sufficient number of tubes containing 20 mL of culture were inoculated with 10µL of culture and incubated 48 - 54 hours at 35 – 37°C. The cultures were allowed to stand for ≥ 10 minutes prior to removing the upper portion of the culture leaving behind clumps and debris and transferring it to a sterile vessel for use in testing. Fetal bovine serum was added to the culture to achieve a final 5% organic soil load. Individual glass slide carriers (18 mm x 36 mm) were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the entire surface of the slide. The carriers were allowed to dry for 32 minutes at 25-30°C at 66% relative humidity. The test carriers were sprayed (using 2 sprays) in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 5 minutes at 21°C at 53% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred to neutralizing solution containing 20 mL of Letheen Broth + 0.14% Lecithin + 1.0% Tween 80. All subcultures were incubated for 48±2 hours at 35-37° and stored at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: No protocol deviations or amendments were required for this study.

4. MRID 490817-17 "AOAC Germicidal Spray Method," Test Organism: *Escherichia coli* (ATCC 11229) for product Vesta, by Joshua Luedtke, M.S. Study conducted at ATS Labs. Study completion date – Sept 6, 2012. Project Number A13384.

The study was conducted against *Escherichia coli* (ATCC 11229). Two lots of test substance, Lot # SS1684 and Lot # SS1685, were tested using the provided ATS Laboratory Protocol No. PG30050312.GS.3 marked as proprietary information. The product was received as ready to use (RTU) trigger spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula submitted with this application. The active ingredient concentration reported on the certificate of analysis (COA) for Lot # SS1684 was 0.2977% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250) and for Lot # SS1685 was 0.2956% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250). A culture of the challenge microorganism was prepared from the initial broth suspension by more than three but

less than thirty daily consecutive transfers of one loopful (10 µL) of culture in 10 mL of the appropriate growth medium Nutrient broth. For the last culture transfer, a suspension of sufficient number of tubes containing 20 mL of culture were inoculated with 10µL of culture and incubated 48 - 54 hours. The cultures were allowed to stand for ≥ 10 minutes prior to removing the upper portion of the culture leaving behind clumps and debris and transferring it to a sterile vessel for use in testing. Fetal bovine serum was added to the culture to achieve a final 5% organic soil load. Individual glass slide carriers (18 mm x 36 mm) were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the entire surface of the slide. The slides were allowed to dry for 30 minutes at 35-37°C at 50% relative humidity. The test carriers were sprayed (using 2 sprays) in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 5 minutes at 21°C at 56% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred to neutralizing media containing 20 mL of Letheen Broth + 0.14% Lecithin + 1.0% Tween 80. All subcultures were incubated for 48±2 hours at 35-37° and were stored at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: No protocol deviations or amendments were required for this study.

5. MRID 490817-18 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: Influenza A Virus, Strain Hong Kong (ATCC VR-544), for product Vesta, by Dawn Pierson, B.S. Study conducted at ATS Labs. Study completion date – June 11, 2012. Project Number A13314.

The study was conducted against Influenza A Virus Strain Hong Kong (ATCC VR-544). Rhesus Monkey Kidney cells (RMK) (obtained from ViroMed Labs) were used as the host cell line. Two lots of test substance, Lot # SS1684 and Lot # SS1685, were tested using the provided ATS Laboratory Protocol No. PG30051112.FLUA marked as proprietary information. The product was received as ready to use (RTU) trigger spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula submitted with this application. The active ingredient concentration reported on the certificate of analysis (COA) for Lot # SS1684 was 0.2977% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250) and for Lot # SS1685 was 0.2956% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250). The stock virus was prepared by collecting the supernatant culture fluid from 75 – 100% infected culture cells that were disrupted and cell debris removed by centrifugation. The high titer stock virus was aliquoted and stored at ≤-70°C until the day of use then an aliquot of the stock virus (ATS Lot F92) was removed and thawed. The stock virus culture was adjusted to contain a final soil load of 5% fetal bovine serum. A 200 µL volume of virus inoculum was spread uniformly over the bottoms of fifteen (15) separate 100 X 15 mm glass Petri dishes. The virus films were dried for 20 minutes until visibly dry at 20.0°C in 40% relative humidity. Each carrier (five carriers per lot) was sprayed with 2 sprays of test substance at a distance of 6 – 8 inches and held for an exposure period of 5 minutes at 20°C. Following exposure, the plates were scraped and the virus-test substance mixtures were immediately passed through individual Sephadex columns. The 10^{-1} dilutions were passed through a second Sephadex column to further detoxify. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution and assayed for

infectivity and/or cytotoxicity. Cells in multi well dishes were inoculated in quadruplicate with 100 µL of the virus-test substance dilutions. The cultures were incubated for seven days at 36 – 38°C with 5 – 7% CO_2 and scored for the absence or presence of cytopathy, cytotoxicity, and viability. Controls included neutralization, cytotoxicity, and input virus control. Titers were calculated using the Spearman Karber method.

Note: No protocol deviations or amendments were required for this study.

6. **MRID 490817-19 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: Influenza A Virus, Strain Hong Kong (ATCC VR-544), for product Vesta, by Shanen Conway, B.S. Study conducted at ATS Labs. Study completion date – Aug 17, 2012. Project Number A13817.**

The study was conducted against Influenza A Virus Strain Hong Kong (ATCC VR-544). Rhesus Monkey Kidney cells (RMK) (obtained from ViroMed Labs) were used as the host cell line. One lot of test substance, Lot # SS1691, was tested using the provided ATS Laboratory Protocol No. PG30071212.FLUA marked as proprietary information. The product was received as ready to use (RTU) trigger spray. The test lot was prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula submitted with this application. The active ingredient concentration reported on the certificate of analysis (COA) for Lot # SS1691 was 0.2985% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250). The stock virus was prepared by collecting the supernatant culture fluid from 75 – 100% infected culture cells that were disrupted and cell debris removed by centrifugation. The high titer stock virus was aliquoted and stored at ≤-70°C until the day of use then an aliquot of the stock virus (ATS Lot F92) was removed and thawed. The stock virus culture was adjusted to contain a final soil load of 5% fetal bovine serum. A 200 µL volume of virus inoculum was spread uniformly over the bottoms of ten (10) separate 100 X 15 mm glass Petri dishes. The virus films were dried for 20 minutes until visibly dry at 20.0°C in 40% relative humidity. Each carrier was sprayed with 2 sprays of test substance at a distance of 6 – 8 inches and held for an exposure period of 5 minutes at 20°C. Following exposure, the plates were scraped and the virus-test substance mixtures were immediately passed through individual Sephadex columns. The 10^{-1} dilutions were passed through two additional Sephadex columns to further detoxify. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. Cells in multi well dishes were inoculated in quadruplicate with 100 µL of the virus-test substance dilutions. The cultures were incubated for seven days at 36 – 38°C with 5 – 7% CO_2 and scored for the absence or presence of cytopathy, cytotoxicity, and viability. Controls included neutralization, cytotoxicity, and input virus control. Titers were calculated using the Spearman Karber method.

Note: No protocol deviations or amendments were required for this study.

7. **MRID 490817-20 "EPA Hard Surface Mildew-Fungistatic Test". Test Organism: *Aspergillus niger* (ATCC 6275) for product Vesta, by Matthew Sathe, B.S. Study conducted at ATS Labs. Study completion date – June 21, 2012. Project Number A13361.**

The study was conducted against *Aspergillus niger* (ATCC 6275). Two lots of test substance, Lot # SS1684 and Lot # SS1685, were tested using the provided ATS

Laboratory Protocol No. PG30050312.MSTAT marked as proprietary information. The product was received as ready to use (RTU) trigger spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula submitted with this application. The active ingredient concentration reported on the certificate of analysis (COA) for Lot # SS1684 was 0.2977% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250) and for Lot # SS1685 was 0.2956% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250). An *Aspergillus niger* conidial suspension was prepared by inoculating Sabouraud Agar (Modified) with stock culture, incubating for 10 days at 25-30°C. Following, saline/Triton Solution (0.85% saline + 0.05% Triton X-100) and glass beads were added to the flask and the flask was agitated to remove mycelia/conidia from the agar. The conidia suspension was aspirated from the flask and filtered through sterile adsorbent cotton guaze to remove the hyphae, then added to a sterile tissue grinder and macerated. The conidial concentration was estimated to be 1.4 X 10^8 conidia/mL using hemacytometer counts. The conidial suspension was standardized to contain a target of 1 x 10^7 conidia per mL by adding a 1 mL aliquot to 20.0 mL sterile Czapek's solution. Fetal bovine serum was added to achieve a 5% organic soil load. Glazed ceramic tile (1" x 1") carriers were sprayed with 2 sprays of test substance for each lot at a distance of 6-8 inches and were placed in a near vertical position to drain excess liquid. The carriers were dried in Petri dishes at 35-37°C for 41 minutes with the lids ajar. Following the drying period of the test substance, an atomizer was used to spray the surface of each test and control carrier with 5 sprays of the *Aspergillus niger* conidia-Czapek suspension. The carriers were placed in Petri dishes and dried at 35-37°C for 39 minutes until visibly dry. Each dried carrier (sprayed side up) was then placed onto an individual water agar plate and incubated for 7 days at 25-30°C in a minimum of 95% relative humidity. The carriers were then observed for the presence or absence of visible fungal growth. When no growth was visually observed, a magnified examination was performed.

Note: No protocol deviations or amendments were required for this study.

8. **MRID 490817-21 "Fabric Mildew-Fungistatic Test". Test Organism: *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333) for product Vesta, by Joshua Luedtke, M.S. Study conducted at ATS Labs. Study completion date – August 29, 2012. Project Number A13651.**

The study was conducted against *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333). Two lots of test substance, Lot # SS1684 and Lot # SS1685, were tested using the provided ATS Laboratory Protocol No. PG30050312.FMSTAT marked as proprietary information. The product was received as ready to use (RTU) trigger spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula submitted with this application. The active ingredient concentration reported on the certificate of analysis (COA) for Lot # SS1684 was 0.2977% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250) and for Lot # SS1685 was 0.2956% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250). An *Aspergillus niger* conidial suspension was prepared by inoculating Sabouraud Agar (Modified) with stock culture, incubating for 10 days at 25-30°C. Following, saline/Triton Solution (0.85% saline + 0.05% Triton X-100) and glass beads were added to the flask and the flask was agitated to remove the mycelia/conidia from the agar. The conidia suspension was filtered through sterile gauze to remove the hyphae, then added to a sterile tissue grinder and macerated. The conidial concentration was estimated to be 1.3 X 10^8 conidia/mL by hemocytometer count. The conidial suspension was standardized to

contain a target of 5 x 10^6 conidia per mL. A *Penicillium variabile* conidial suspension was prepared by inoculating Potato Dextrose Agar with stock culture, incubating for 10 days at 25-30°C. Following, 2.0 mL of saline/Triton Solution (0.85% saline + 0.05% Triton X-100) was added to each plate and the growth was harvested from the agar surface using a cell scraper. The suspension was transferred to a vessel containing beads, shaken thoroughly, and filtered through sterile gauze to remove the hyphae, then added to a sterile tissue grinder and macerated. The conidial concentration was estimated to be 9.15 X 10^8 conidia/mL by hemocytometer count. The conidial suspension was standardized to contain a target of 5 x 10^6 conidia per mL. Equal volumes (20.0 mL) of each well-mixed conidial suspension were combined and a 2.00 mL aliquot of FBS was added to 38.0 mL of the combined organism suspension to yield a 5% fetal bovine serum soil load. Carriers of cotton muslin fabric cut approximately 25 mm by 75 mm strips from 136 to 203 g/m^2 (4 to 6 oz/ yd^2) cotton muslin were autoclave-sterilized. Polyester fabric carriers were cut as approximately 25 mm by 75 mm strips and were autoclave sterilized. The sterilized fabric carriers were saturated with sterile glycerol nutrient solution by soaking for approximately three minutes until saturated and allowed to dry prior to inoculation. For each lot of test substance, each side of 10 test carriers were inoculated with 2 sprays of the test substance at a distance of 6-8 inches. The treated carriers were placed in a vertical or near vertical position to permit excess liquid to drain. The carriers were dried at room temperature (22.1-22.4°C) for 3 hours until dry. A 25.0 mL aliquot of combined organism suspension/soil load was transferred to a DeVilbiss atomizer for inoculation of carriers. Both sides of each fabric test carrier strip were lightly sprayed with the combined organism suspension/soil load using 10 sprays. The fabric test and control samples were suspended in individual 250 mL French Square bottles containing approximately 10 mL sterile deionized water and incubated at 25-30°C. The caps were tightened and then backed off approximately 1/8 turn to allow for ventilation. It was ensured that no fabric was touching the water at the time of incubation. The control plates and organic soil load sterility control were incubated for 2 days at 25-30°C. Observations were made and recorded every 7 days for three weeks. The presence or absence of observable mold on the test carriers was the criterion for determining effectiveness of the test product. Controls included those for initial suspension count, carrier population count, purity, sterility, and neutralization confirmation.

Note: The growth medium for *Penicillium variabile* culture preparation was Potato Dextrose Agar which differs from the protocol that indicates the use of Sabouraud Dextrose Agar which did not impact the efficacy test.

9. MRID 490817-22 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)" Test Organisms: *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538) for product Vesta, by Anne Stemper, B.S. Study conducted at ATS Labs. Study completion date – May 17, 2013. Project Number A14923.

The study was conducted against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538). Three lots, Lot # SS1684, Lot # SS1685, and Lot # SS1691 (≥60 days old), of test substance were tested using the provided ATS Laboratory Protocol No. PG30042513.NFS marked as proprietary information. The product was received as ready to use (RTU) trigger spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula

submitted with this application. The active ingredient concentration reported on the certificate of analysis (COA) for Lot # SS1684 was 0.2977% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250), for Lot # SS1685 was 0.2956% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250), and for Lot # SS1691 was 0.2985% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250). A culture of the challenge microorganism was prepared from the initial broth suspension by more than three but less than thirty daily consecutive transfers of one loopful (10 µL) of culture in 10 mL of the appropriate growth medium of Trypic Soy Broth for *E. aerogenes* and Nutrient broth for *S. aureus*. The last culture transfer suspension was incubated 48 hours, vortex-mixed, and allowed to stand for ≥ 15 minutes prior to removing the upper 2/3rds portion of the culture and transferring it to a sterile vessel for use in testing. Fetal bovine serum was added to the culture to achieve a final 5% organic soil load. Individual glass slide carriers (1"x1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread to within 3 mm of the edges of the carriers. The carriers were allowed to dry for 35 minutes at 35-37°C at 40% relative humidity in a constant humidity chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a dessicator after opening. For each lot of test substance, 5 test carriers per test organism were sprayed (using 2 sprays) in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 5 minutes at 21°C at 37% relative humidity. Following the exposure period, the individual carriers were transferred into neutralizing solution containing 20 mL of Letheen Broth + 0.07% Lecithin + 0.5% Tween 80. For *Enterobacter aerogenes*, within 30 minutes of neutralization, duplicate 1 mL and 0.100 mL aliquots of the neutralized solution (10^0) were plated onto the recovery agar Tryptic Soy Agar with 5% Sheep Blood. For *Staphylococcus aureus*, within 30 minutes of neutralization, duplicate 1 mL and 0.100 mL aliquots of the neutralized solution were transferred to individual filter units pre-wetted with 10.0 mL of sterile diluents. The contents were evacuated and each filter was rinsed ≥ 50 mL of sterile diluents. Each filter was transferred to the recovery agar medium Tryptic Soy Agar with 5% Sheep Blood. The *Staphylococcus aureus* plates were incubated for 48 hours at 35-37°. The *Enterobacter aerogenes* plates were incubated for 48 hours at 25-30°. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: No protocol deviations or amendments were required for this study.

10. MRID 490817-23 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application)" Test Organisms: *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538) for product Vesta, by Jill Ruhme, B.S. Study conducted at ATS Labs. Study completion date – September 5, 2012. Project Number A13411.

The study was conducted against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538). Two lots of test substance, Lot # SS1684 and Lot # SS1685, of test substance were tested using the provided ATS Laboratory Protocol No. PG30050312.NFS.1 marked as proprietary information. The product was received as ready to use (RTU) trigger spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula submitted with this application. The active ingredient concentration reported on the certificate of analysis

(COA) for Lot # SS1684 was 0.2977% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250) and for Lot # SS1685 was 0.2956% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250). A culture of the challenge microorganism was prepared from the initial broth suspension by more than three but less than thirty daily consecutive transfers of one loopful (10 µL) of culture in 10 mL of the appropriate growth medium of Trypic Soy Broth for *E. aerogenes* and Nutrient broth for *S. aureus*. The last culture transfer suspension was incubated 48 hours, vortex-mixed, and allowed to stand for ≥ 15 minutes prior to removing the upper 2/3rds portion of the culture and transferring it to a sterile vessel for use in testing. Fetal bovine serum was added to the culture to achieve a final 5% organic soil load. Scouring of the fabric carriers was performed before inoculation with test organisms. For the plain cotton weave fabric for testing, a scouring solution was prepared by adding 6.0331 grams of Na_2C0_3 and 6.1295 grams of Triton X-100 to 12 L of deionized water. For the fabric plain cotton weave, 80 x 80 threads/inch, a 1206.88 gram sample of test fabric was added to 12 L of scouring solution. For the 100% Dacron polyester fabric for testing, a scouring solution was prepared by adding 0.4032 grams of Na_2C0_3 and 0.4199 grams of Triton X-100 to 0.8 L of deionized water. For the polyester fabric for testing, an 80.20 gram sample of test fabric was added to 0.8 L of scouring solution. The scouring solutions containing fabric (carriers) were allowed to boil for approximately 60 minutes followed by removal and subsequent rinsing in boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The fabric carriers were cut to a size of approximately 1"x 1" and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Individual fabric carriers (1"x1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculated carriers were allowed to dry for 20 minutes at 35-37°C at 40% relative humidity. Following, for each lot of test substance, 5 test carriers each of cotton and polyester for each test organism were sprayed (using 2 sprays) in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 5 minutes at room temperature (21°C) at 43-62% relative humidity in Petri dishes. Following the exposure period, the individual carriers were transferred to neutralizing solution containing Letheen Broth + 1.0% Lecithin + 9.0% Tween 80 for testing done on June 12, 2012 or Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 for testing done on July 6, 2012. Following neutralization, the excess liquid in each Petri dish was transferred to the neutralization jar containing the corresponding carrier and vortex with glass beads to aid in organism recovery. Within 30 minutes of neutralization, aliquots of the neutralization solution, including serial dilutions were plated onto recovery agar plate medium of Tryptic Soy Agar with 5% Sheep Blood. For *E. aerogenes,* duplicate 1.0 mL and 0.100 mL aliquots of the neutralized solution was plated. For *S. aureus* cotton carriers for Lot SS1685 performed on June 12, 2012, duplicate 1.0 mL aliquots and 1.0mL aliquots of a ten-fold serial dilution were plated. For *S. aureus* testing performed on July 06, 2012, duplicate 1.0 mL and 0.10 mL aliquots of the neutralized solution were transferred to individual filter units pre-wetted with 10 mL of sterile diluents and the contents were evacuated. The filter was rinsed with ≥50 mL of sterile diluent and transferred to the recovery agar medium. The *S. aureus* plates and subcultures were incubated at 35-37° for 48±4 hours. The *E. aerogenes* plates and subcultures were incubated for 48±4 hours at 25-30°C. For testing performed on July 6, 2012, the *S. aureus* subcultures were placed at 2 – 8°C for 3 days prior to examination. Plates and subcultures were visually examined for the presence or absence of growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Due to neutralization control failure of *S. aureus*, the assay was repeated on July 6, 2012 with Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 as the neutralizing solution. The repeated *S. aureus* assay is valid.

11. MRID 490817-24 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application)" Test Organisms: *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538) for product Vesta, by Anne Stemper, B.S. Study conducted at ATS Labs. Study completion date – October 12, 2012. Project Number A13830.

The study was conducted against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538). One lot of test substance, Lot # SS1691, of test substance was tested using the provided ATS Laboratory Protocol No. PG30071212.NFS marked as proprietary information. The product was received as ready to use (RTU) trigger spray. The test lot was prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula submitted with this application. The active ingredient concentration reported on the certificate of analysis (COA) for Lot # SS1691 was 0.2985% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250). A culture of the challenge microorganism was prepared from the initial broth suspension by more than three but less than thirty daily consecutive transfers of one loopful (10 µL) of culture in 10 mL of the appropriate growth medium of Trypic Soy Broth for *E. aerogenes* and Nutrient broth for *S. aureus*. The last culture transfer suspension was incubated 48 hours, vortex-mixed, and allowed to stand for ≥ 15 minutes prior to removing the upper 2/3rds portion of the culture and transferring it to a sterile vessel for use in testing. Fetal bovine serum was added to the culture to achieve a final 5% organic soil load. Scouring of the fabric carriers was performed before inoculation with test organisms. For the plain cotton weave fabric for testing, a scouring solution was prepared by adding 2.8531 grams of Na_2C0_3 and 2.8519 grams of Triton X-100 to 5.7 L of deionized water. For the fabric plain cotton weave, 80 x 80 threads/inch, a 568.88 gram sample of test fabric was added to 5.7 L of scouring solution. For the 100% Dacron polyester fabric for testing, a scouring solution was prepared by adding 2.1211 grams of Na_2C0_3 and 2.1502 grams of Triton X-100 to 4.2 L of deionized water. For the fabric for testing of polyester, a 417.78 gram sample of test fabric was added to 4.2 L of scouring solution. The scouring solutions containing fabric (carriers) were allowed to boil for approximately 60 minutes followed by removal and subsequent rinsing in boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The fabric carriers were cut to a size of approximately 1"x 1" and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Individual fabric carriers (1"x1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculated carriers were allowed to dry for 20 minutes at 35-37°C at 40% relative humidity. Five (5) test carriers each of cotton and polyester for each test organism were sprayed (using 2 sprays) in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 5 minutes at 20°C at 61% relative humidity in Petri dishes. Following the exposure period, the individual carriers were transferred to neutralizing solution containing Letheen Broth + 0.28% Lecithin + 2.0% Tween 80 for testing done on August 9, 2012 or Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 for testing done on

September 4, 2012. Following neutralization, the excess liquid in each Petri dish was transferred to the neutralization jar containing the corresponding carrier and vortex-mixed. Within 30 minutes of neutralization, aliquots of the neutralization solution, including serial dilutions were plated onto recovery agar plate medium of Tryptic Soy Agar with 5% Sheep Blood. For *E. aerogenes* testing done on August 9, 2012, duplicate 1.0 mL and 0.100 mL aliquots of the neutralized solution was plated. For *S. aureus* testing performed on September 04, 2012, duplicate 1.0 mL and 0.10 mL aliquots of the neutralized solution were transferred to individual filter units pre-wetted with 10 mL of sterile diluent and the contents were evacuated. The filter was rinsed with ≥50 mL of sterile diluents and transferred to the recovery agar medium. The *S. aureus* plates and subcultures were incubated at 35-37° for 48±4 hours. The *E. aerogenes* plates and subcultures were incubated for 48±4 hours at 25-30°C. Plates and subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Due to neutralization control failure of *S. aureus*, the assay was repeated on September 4, 2012 with Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 as the neutralizing solution. The repeated *S. aureus* assay is valid.

12. MRID 490817-25 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application)" Test Organism: *Staphylococcus aureus* (ATCC 6538) for product Vesta by Anne Stemper, B.S. Study conducted at ATS Labs. Study completion date – May 17, 2013. Project Number A14755.

The study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots of test substance, Lot # SS1684, Lot # SS1685, and Lot # SS1691 (≥60 days old), of test substance were tested using the provided ATS Laboratory Protocol No. PG30030413.NFS marked as proprietary information. The product was received as ready to use (RTU) trigger spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula submitted with this application. The active ingredient concentration reported on the certificate of analysis (COA) for Lot # SS1684 was 0.2977% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250), for Lot # SS1685 was 0.2956% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250), and for Lot # SS1691 was 0.2985% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250). A culture of the challenge microorganism was prepared from the initial broth suspension by more than three but less than thirty daily consecutive transfers of one loopful (10 µL) of culture in 10 mL of the appropriate growth medium of Nutrient broth. The last culture transfer suspension was incubated 48-54 hours, vortex-mixed, and allowed to stand for ≥ 15 minutes prior to removing the upper 2/3rds portion of the culture and transferring it to a sterile vessel for use in testing. Fetal bovine serum was added to the culture to achieve a final 5% organic soil load. Scouring of the fabric carriers was performed before inoculation with the test organism. For the plain cotton weave fabric, 80 x 80 threads/inch, a scouring solution was prepared by adding 2.8531 grams of Na_2C0_3 and 2.8519 grams of Triton X-100 to 5.7 L of deionized water. A 568.88 gram sample of test fabric was added to 5.7 L of scouring solution. To prepare the 100% Dacron polyester fabric for testing, a scouring solution was prepared by adding 2.1211 grams of Na_2C0_3 and 2.1502 grams of Triton X-100 to 4.2 L of deionized water. A 417.78 gram sample of test fabric was added to 4.2 L of scouring solution. The scouring solutions containing fabric (carriers) were allowed to boil for approximately 60 minutes followed by removal and subsequent rinsing in boiling

water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The fabric carriers were cut to a size of approximately 1"x 1" and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Individual fabric carriers (1"x1"), each in a Petri dish, were inoculated with 30.0 µL of test organism using a calibrated pipettor. The inoculated carriers were allowed to dry for 20 minutes at 35-37°C at 39% relative humidity. For each lot of test substance, 5 test carriers each of cotton and polyester were sprayed (using 2 sprays) in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 5 minutes at room temperature (20°C) at 17% relative humidity in Petri dishes. Following the exposure period, the individual carriers were transferred to neutralizing solution containing 20 mL of Letheen Broth + 0.07% Lecithin + 0.5% Tween 80. Following neutralization, the liquid in each Petri dish was transferred with each carrier to a neutralization jar and vortex-mixed. Within 30 minutes of neutralization, 1.0 mL and 0.10 mL aliquots of the neutralization solution were transferred to individual filter units pre-wetted with 10 mL of sterile 0.85% saline and the contents were evacuated. The filter was rinsed with ≥50 mL of sterile 0.85% saline and transferred to the recovery agar medium of Tryptic Soy Agar with 5% Sheep Blood. The plates and subcultures were incubated at 35-37° for 48±4 hours prior to an examination for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: No protocol deviations or amendments were required for this study.

13. MRID 490817-26 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application)" Test Organism: *Escherichia coli* (ATCC 11229) for product Vesta by Anne Stemper, B.S. Study conducted at ATS Labs. Study completion date – June 29, 2012. Project Number A13412.

The study was conducted against *Escherichia coli* (ATCC 11229). Two lots of test substance, Lot # SS1684 and Lot # SS1685, of test substance were tested using the provided ATS Laboratory Protocol No. PG30050312.NFS.2 marked as proprietary information. The product was received as ready to use (RTU) trigger spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula submitted with this application. The active ingredient concentration reported on the certificate of analysis (COA) for Lot # SS1684 was 0.2977% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250) and for Lot # SS1685 was 0.2956% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250). A culture of the challenge microorganism was prepared from the initial broth suspension by more than three but less than thirty daily consecutive transfers of one loopful (10 µL) of culture in 10 mL of the appropriate growth medium of Nutrient broth. The last culture transfer suspension was incubated 48-54 hours, vortex-mixed, and allowed to stand for ≥ 15 minutes prior to removing the upper 2/3rds portion of the culture and transferring it to a sterile vessel for use in testing. Fetal bovine serum was added to the culture to achieve a final 5% organic soil load. Scouring of the fabric carriers was performed before inoculation with the test organism. For the plain cotton weave fabric, 80 x 80 threads/inch, a scouring solution was prepared by adding 6.0331 grams of Na_2C0_3 and 6.1295 grams of Triton X-100 to 12 L of deionized water. A 1206.88 gram sample of test fabric was added to 12 L of scouring solution. To prepare the 100% Dacron polyester

fabric for testing, a scouring solution was prepared by adding 0.4032 grams of Na_2C0_3 and 0.4199 grams of Triton X-100 to 0.8 L of deionized water. An 80.20 gram sample of test fabric was added to 0.8 L of scouring solution. The scouring solutions containing fabric (carriers) were allowed to boil for approximately 60 minutes followed by removal and subsequent rinsing in boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The fabric carriers were cut to a size of approximately 1"x 1" and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Individual fabric carriers (1"x1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculated carriers were allowed to dry for 20 minutes at 35-37°C at 40% relative humidity. For each lot of test substance, 5 test carriers each of cotton and polyester were sprayed (using 2 sprays) in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 5 minutes at room temperature (20°C) at 43% relative humidity. Following the exposure period, the individual carriers were transferred to neutralizing solution containing 20 mL of Letheen Broth + 1.0% Lecithin + 9.0% Tween 80. Following neutralization, the liquid in each Petri dish was transferred with each carrier to a neutralization jar and vortex-mixed. Within 30 minutes of neutralization, 1.0 mL and 0.10 mL aliquots of the neutralization solution were plated onto Tryptic Soy agar plates containing 5% sheep blood. The plates and subcultures were incubated at 35-37° for 48±4 hours prior to an examination for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: No protocol deviations or amendments were required for this study.

14. MRID 490817-27 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application)" Test Organism: *Proteus mirabilis* (ATCC 7002) for product Vesta, by Anne Stemper, B.S. Study conducted at ATS Labs. Study completion date – June 29, 2012. Project Number A13413.

The study was conducted against *Proteus mirabilis* (ATCC 7002). Two lots of test substance, Lot # SS1684 and Lot # SS1685, of test substance were tested using the provided ATS Laboratory Protocol No. PG30050312.NFS.3 marked as proprietary information. The product was received as ready to use (RTU) trigger spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula submitted with this application. The active ingredient concentration reported on the certificate of analysis (COA) for Lot # SS1684 was 0.2977% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250) and for Lot # SS1685 was 0.2956% Didecyl Dimethyl Ammonium Chloride (listed as Bardac 2250). A culture of the challenge microorganism was prepared from the initial broth suspension by more than three but less than thirty daily consecutive transfers of one loopful (10 µL) of culture in 10 mL of the appropriate growth medium of Nutrient broth. The last culture transfer suspension was incubated 48-54 hours, vortex-mixed, and allowed to stand for ≥ 15 minutes prior to removing the upper 2/3rds portion of the culture and transferring it to a sterile vessel for use in testing. Fetal bovine serum was added to the culture to achieve a final 5% organic soil load. Scouring of fabric carriers was performed before inoculation with the test organism. For the plain cotton weave fabric, a scouring solution was by adding 6.0331 grams of Na_2C0_3 and 6.1295 grams of Triton X-100 to 12 L of

deionized water. A 1206.88 gram sample of test fabric was added to 12 L of scouring solution. To prepare the 100% Dacron polyester fabric for testing, a scouring solution was prepared by adding 0.4032 grams of Na_2C0_3 and 0.4199 grams of Triton X-100 to 0.8 L of deionized water. An 80.20 gram sample of test fabric was added to 0.8 L of scouring solution. The scouring solutions containing fabric (carriers) were allowed to boil for approximately 60 minutes followed by removal and subsequent rinsing in boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The fabric carriers were cut to a size of approximately 1"x 1" and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Individual fabric carriers (1"x1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculated carriers were allowed to dry for 20 minutes at 35-37°C at 40-41% relative humidity. For each lot of test substance, 5 test carriers each of cotton and polyester were sprayed (using 2 sprays) in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 5 minutes at room temperature (20°C) at 41% relative humidity. Following the exposure period, the individual carriers were transferred to neutralizing solution containing 20 mL of Letheen Broth + 1.0% Lecithin + 9.0% Tween 80. Following neutralization, the liquid in each Petri dish was transferred with each carrier to a neutralization jar and vortex-mixed. Within 30 minutes of neutralization, 1.0 mL and 0.10 mL aliquots of the neutralization solution were plated onto MacConkey agar. The plates and subcultures were incubated at 35-37° for 48±4 hours prior to an examination for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: No protocol deviations or amendments were required for this study.

V. RESULTS:

Efficacy of a Disinfectant for Use on Hard Surfaces					
MRID Number	**Organism**	**No. Exhibiting Growth/Total No. Carriers Tested**			**Carrier Population (Log_{10}CFU/ Carrier)**
		Lot SS1684	**Lot SS1685**	**Lot SS1691**	
		5 Minute Exposure Time			
490817-14	*Salmonella enterica* (ATCC 10708)	0/60	0/60	----	5.79
	Staphylococcus aureus (ATCC 6538)	0/60	0/60	----	5.74
490817-15	*Salmonella enterica* (ATCC 10708)	----	----	0/60	6.26
	Staphylococcus aureus (ATCC 6538)	----	----	0/60	5.91
490817-16	*Proteus mirabilis* (ATCC 7002)	0/10	0/10	----	6.34
490817-17	*Escherichia coli* (ATCC 11229)	0/10	0/10	----	6.74

	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces						
MRID Number	**Organism**	**Results – 5 Minute Exposure**				**Log_{10} Reduction**	**Dried Virus Control (Average of 5 replicates)**
		Dilution	**Lot SS1684**	**Lot SS1685**	**Lot SS1691**		
490817-18	Influenza A Virus, Strain Hong Kong (ATCC VR-544)	10^{-1} to 10^{-7}	Complete Inactivation	Complete Inactivation	----		$10^{5.18}$ $TCID_{50}$/100µL
		$TCID_{50}$/100µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	----	≥4.68 For both lots	
490817-19	Influenza A Virus, Strain Hong Kong (ATCC VR-544)	10^{-1} to 10^{-7}	----	----	Complete Inactivation		$10^{5.43}$ $TCID_{50}$/100µL
		$TCID_{50}$/100µL	----	----	$\leq 10^{0.50}$	≥4.93	

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Carrier Population (Pass/Fail)
		Lot No. SS1684	Lot No. SS1685	
Hard, Non-Porous Surface Mildew-Fungistatic Test - 7 Day				
490817-20	*Aspergillus niger* (ATCC 6275)	0/10	0/10	PASS All control carriers contained ≥50% growth coverage.

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Initial Conidial Suspension Control (CFU/mL)	Visual Evaluation of Untreated Control Carriers
		Lot # SS1684	Lot # SS1685		
Soft Surface Mildew-Fungistatic Test - Cotton Muslim					
490817-21	*Aspergillus niger* (ATCC 6275)	Day 7 = 0/10 Day 14 = 0/10 Day 21 = 3/10	Day 7 = 0/10 Day 14 = 0/10 Day 21 = 3/10	2.6×10^6	All ten carriers for each batch and at each time period demonstrated ≥50% growth
	Penicillium variabile (ATCC 32333)	Day 7 = 0/10 Day 14 = 0/10 Day 21 = 3/10	Day 7 = 0/10 Day 14 = 0/10 Day 21 = 3/10	5.2×10^6	All ten carriers for each batch and at each time period demonstrated ≥50% growth
Soft Surface Mildew-Fungistatic Test - Polyester					
490817-21	*Aspergillus niger* (ATCC 6275)	Day 7 = 0/10 Day 14 = 0/10 Day 21 = 1/10	Day 7 = 0/10 Day 14 = 0/10 Day 21 = 3/10	2.6×10^6	All ten carriers for each batch and at each time period demonstrated ≥50% growth
	Penicillium variabile (ATCC 32333)	Day 7 = 0/10 Day 14 = 0/10 Day 21 = 1/10	Day 7 = 0/10 Day 14 = 0/10 Day 21 = 3/10	5.2×10^6	All ten carriers for each batch and at each time period demonstrated ≥50% growth

MRID Number	Organism	Lot No.	Average No. Surviving	Microbes Initially Present	Percent Reduction
			CFU/Carrier		
5-Minute Exposure Time (Non-Food Contact Sanitizer for Hard Non-porous Surfaces)					
490817-22	*Enterobacter aerogenes* (ATCC 13048)	SS1684 SS1685 SS1691*	$<2 \times 10^1$ $<2 \times 10^1$ $<2 \times 10^1$	1.78×10^7 1.78×10^7 1.78×10^7	>99.9 >99.9 >99.9
	Staphylococcus aureus (ATCC 6538)	SS1684 SS1685 SS1691*	$<2 \times 10^1$ $<2 \times 10^1$ $<2 \times 10^1$	3.02×10^6 3.02×10^6 3.02×10^6	>99.9 >99.9 >99.9

*≥60 Days old

MRID Number	Organism	Lot No.	Average No. Surviving	Microbes Initially Present	Percent Reduction
			CFU/Carrier		
5-Minute Exposure Time (Soft Surface, Non-Food Contact Sanitizer)					
Plain Cotton Fabric					
490817-23	*Enterobacter aerogenes* (ATCC 13048) Test Date: 6/12/12	SS1684 SS1685	$<2 \times 10^1$ $<2 \times 10^1$	1.23×10^6 1.23×10^6	>99.9 >99.9
	Staphylococcus aureus (ATCC 6538) Test Date: 7/6/12	SS1684 SS1685	$<2 \times 10^1$ $<2 \times 10^1$	4.37×10^5 4.37×10^5	>99.9 >99.9
490817-24	*Enterobacter aerogenes* (ATCC 13048) Test Date: 8/9/12	SS1691	$<2 \times 10^1$	1.48×10^6	>99.9
	Staphylococcus aureus (ATCC 6538) Test Date: 9/4/12	SS1691	$<2 \times 10^1$	3.63×10^5	>99.9
490817-25	*Staphylococcus aureus* (ATCC 6538)	SS1684 SS1685 SS1691*	$<2 \times 10^1$ $<2 \times 10^1$ $<2 \times 10^1$	1.02×10^6 1.02×10^6 1.02×10^6	>99.9 >99.9 >99.9
490817-26	*Escherichia coli* (ATCC 11229)	SS1684 SS1685	$<2 \times 10^1$ $<2 \times 10^1$	1.35×10^6 1.35×10^6	>99.9 >99.9
490817-27	*Proteus mirabilis* (ATCC 7002)	SS1684 SS1685	$<2 \times 10^1$ $<2 \times 10^1$	1.62×10^6 1.62×10^6	>99.9 >99.9
Polyester Fabric					
490817-23	*Enterobacter aerogenes* (ATCC 13048) Test Date: 6/12/12	SS1684 SS1685	$<2 \times 10^1$ $<2 \times 10^1$	1.07×10^7 1.07×10^7	>99.9 >99.9
	Staphylococcus aureus (ATCC 6538) Test Date: 7/6/12	SS1684 SS1685	$<2 \times 10^1$ $<2 \times 10^1$	1.95×10^6 1.95×10^6	>99.9 >99.9
490817-24	*Enterobacter aerogenes* (ATCC 13048) Test Date: 8/9/12	SS1691	$<2 \times 10^1$	5.13×10^6	>99.9 >99.9
	Staphylococcus aureus (ATCC 6538) Test Date: 9/4/12	SS1691	$<2 \times 10^1$	4.47×10^5	>99.9 >99.9

MRID Number	Organism	Lot No.	Average No. Surviving	Microbes Initially Present	Percent Reduction
			CFU/Carrier		
490817-25	*Staphylococcus aureus* (ATCC 6538)	SS1684 SS1685 SS1691*	$<2 \times 10^1$ $<2 \times 10^1$ $<2 \times 10^1$	3.39×10^6 3.39×10^6	>99.9 >99.9
490817-26	*Escherichia coli* (ATCC 11229)	SS1684 SS1685	$<2 \times 10^1$ $<2 \times 10^1$	1.35×10^7 1.35×10^7	>99.9 >99.9
490817-27	*Proteus mirabilis* (ATCC 7002)	SS1684 SS1685	$<2 \times 10^1$ $<2 \times 10^1$	6.61×10^6 6.61×10^6	>99.9

*≥60 Days old

VI. CONCLUSIONS:

1. The submitted efficacy data **support** the use of the ready to use spray product Vesta as a broad spectrum disinfectant on hard, non-porous surfaces in the presence of a 5% organic soil load for a 5-minute contact time for the following microorganisms:

Salmonella enterica (ATCC 10708) MRID 490817-14 & MRID 490817-15
Staphylococcus aureus (ATCC 6538) MRID 490817-14 & MRID 490817-15
Proteus mirabilis (ATCC 7002) MRID 490817-16
Escherichia coli (ATCC 11229) MRID 490817-17

Acceptable killing was observed in the subcultures of the required number of carriers tested using the required number of product lots. All tested product lots active ingredient were at the lower certified limit. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Neutralization confirmation testing showed positive growth of the microorganisms.

2. The submitted efficacy data **support** the use of the ready to use spray product Vesta as a disinfectant with virucidal activity on hard, non-porous surfaces in the presence of a 5% organic soil load for a 5-minute contact time for the following microorganism:

Influenza A Virus, Strain Hong Kong (ATCC VR-544) MRID 490817-18-19

Complete inactivation was demonstrated. Input virus controls demonstrated positive growth. Cytotoxicity controls and neutralization control showed growth beyond the cytotoxic level.

3. The submitted efficacy data **support** the use of the ready to use spray product Vesta as a Hard Surface Mildew Fungistat (not fungicide) on hard, non-porous surfaces in the presence of a 5% organic soil load for a 7day period for the following microorganism:

Aspergillus niger (ATCC 6275) MRID 490817-20

There was not any visual growth on the appropriate number of carriers with the appropriate number of tested batches of product after a seven day period. Culture demonstrated purity. Sterility controls demonstrated no growth. The control carriers showed at least 50% fungal growth after 7 days.

4. The submitted efficacy data **support** the use of the ready to use spray product Vesta as a Fabric Mildew Fungistat (not fungicidal) on cotton muslin fabric and polyester fabric in the presence of a 5% organic soil load for a 7 and 14 days period (not 21 day period) for the following microorganisms:

Aspergillus niger (ATCC 6275)	MRID 490817-21
Penicillium variabile (ATCC 32333)	MRID 490817-21

All required number of carriers was free of fungal growth for 7 and 14 days. Culture demonstrated purity. Sterility controls demonstrated no growth. The control carriers showed at least 50% fungal growth after 7, 14, and 21 days.

5. The submitted efficacy data **support** the use of the ready to use spray product Vesta as a sanitizer on non-food contact hard non-porous surfaces in the presence of a 5% organic soil load for a 5-minute contact time for the following microorganism:

Enterobacter aerogenes (ATCC 13048)	MRID 490817-22
Staphylococcus aureus (ATCC 6538)	MRID 490817-22

Results show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. Neutralization control demonstrated growth. Purity controls were reported as pure. Sterility controls did not show growth.

6. The submitted efficacy data **support** the use of the ready to use spray product Vesta as a Spot Soft Surface Sanitization on soft, inanimate, non-food contact surfaces of cotton and polyester in the presence of a 5% organic soil load for a 5-minute contact time for the following microorganisms:

Enterobacter aerogenes (ATCC 13048)	MRID 490817-23 & -24
Staphylococcus aureus (ATCC 6538)	MRID 490817-23, -24, -25
Proteus mirabilis (ATCC 7002)	MRID 490817-26
Escherichia coli (ATCC 11229)	MRID 490817-27

Acceptable killing was observed using the required number of product lots in the subcultures of two types of fabric (cotton and polyester). Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Neutralization confirmation testing showed positive growth of the microorganisms.

VII. RECOMMENDATIONS:

1. The label claims that the ready to use spray product Vesta is an effective broad spectrum disinfectant on hard, non-porous surfaces for a 5-minute contact time against the following organisms:

Salmonella enterica (ATCC 10708)
Staphylococcus aureus (ATCC 6538)
Proteus mirabilis (ATCC 7002)
Escherichia coli (ATCC 11229
Influenza A Virus, Strain Hong Kong (ATCC VR-544)

These claims are **acceptable** as they are supported by the submitted data.

2. The label claims that the ready to use spray product Vesta provides Hard Surface Mildew Fungistatic (not fungicidal) activity on hard, non-porous surfaces for a 5 minute contact time for a 7 day period against the following organism:

Aspergillus niger (ATCC 6275)

These claims are **acceptable** as they are supported by the submitted data.

3. The label claims that the ready to use spray product Vesta provides Fabric Mildew Fungistatic (not fungicidal) activity on cotton and polyester fabrics for a 7 and 14 day periods against the following organisms:

Aspergillus niger (ATCC 6275)
Penicillium variable (ATCC 32333)

These claims are **acceptable** as they are supported by the submitted data.

4. The label claims that the ready to use spray product Vesta is an effective non-food contact sanitizer against the following organisms on hard non-porous surfaces for a 5-minute contact time:

Enterobacter aerogenes (ATCC 13048)
Staphylococcus aureus (ATCC 6538)

These claims are **acceptable** as they are supported by the submitted data.

5. The label claims that the ready to use spray product Vesta, provides Spot Soft Surface Sanitization on soft, non-food contact surfaces for a 5-minute contact period against the following organisms:

Staphylococcus aureus (ATCC 6538)
Enterobacter aerogenes (ATCC 13048)
Proteus mirabilis (ATCC 7002)
Escherichia coli (ATCC 11229

These claims are **acceptable** as they are supported by the submitted data.

LABEL RECOMMENDATIONS:

Note to PM: For Spot Soft Surface Sanitization claims, the label must indicate For Spot Soft surface sanitizing treatment.

- Page 1 under disinfection directions, Remove *Enterobacter aerogenes* (ATCC 13048) from disinfection claims. The submitted efficacy testing did not support these claims. Data only supports sanitization claims for *Enterobacter aerogenes* (ATCC 13048).
- Page 1 under For mold/mildew prevention, Rewrite "Repeat treatment every 14 days," to state "Repeat treatment every 7 days," The data submitted only supports a 7 day treatment period for hard non-porous surfaces.
- Page 2 under soft surface sanitization, Remove "Multipurpose sanitizer". This statement is false and misleading. It implies heightened efficacy.
- Page 2 under soft surface sanitization, Remove "(get rid of)". It implies heightened sanitization efficacy which demonstrates a reduction of >99.9% of organisms and not complete killing.
- Page 2 and 3 under soft surface sanitization, Remove all claims associated with "penetrating/penetrates", "hide", and "hiding deep inside". The studies support spot soft surface sanitization. Claims are limited to fabric surfaces.
- Page 2 and 3 under soft surface sanitization, Remove "(rugs)", "carpets", and "(hotel carpets)". The claims are limited to fabrics. Rugs and carpets are composed of many fabrics with different pile types and densities which is not tested in the submitted studies.
- Page 3, Remove "kills bacteria" from the mold/mildew claims. This statement is false and misleading. Fungistatic activity inhibits and prevents mold and mildew growth.
- Page 3 and 4 under soft surface sanitization and hard surface sanitization, Remove all statements of "Remove", "(killer)", "(reducer)" or qualify by stating "Remove 99.9%", "killer of 99.9%", "reducer of 99.9%". The word Remove alone implies to take away or off completely which is a heightened sanitization efficacy claim. The words killer and reducer needs to be qualified.
- Page 4 under hard surface sanitization, Remove "kills without bleach". This is a comparison claim.
- Page 5 under hard surface disinfection, Remove "Multi surface". The product has been approved for disinfection on hard non-porous surfaces.